K101700
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510(k) Summary of Safety and Effectiveness:

EXTREMITY MEDICAL Screw and Washer Implant System

Submitter:	EXTREMITY MEDICAL 300 Interpace Parkway Suite 410 Parsippany, NJ 07054 OCT 12 2010
Contact Person	Jamy Gannoe President Phone: (973) 588-8980 Email: jgannoe@extremitymedical.com
Date Prepared	September 15, 2010
Trade Name	EXTREMITY MEDICAL Screw and Washer System
Classification Name and Number	Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040
Product Code	HWC
Predicate Devices	1. EXTREMITY MEDICAL Compression Screw System, EXTREMITY MEDICAL K081934 2. 3.0 Cannulated Screw and Threaded Washer , Synthes K962823 3. EXTREMITY MEDICAL Midfoot Screw System, EXTREMITY MEDICAL K082934
Device Description	The EXTREMITY MEDICAL Screw and Washer System consists of a lag screw of five various diameters and lengths ranging from 10 to 100mm, as well as a mating washer component consisting of five various diameters and lengths ranging from 14 to 50mm. Both implant components are manufactured from Titanium alloy.
Indications for use	The EXTREMITY MEDICAL Screw and Washer System is intended for reduction and internal fixation of arthrodeses, osteotomies, intra- and extrarticular fractures and nonunions of the small bones and joints of the foot, ankle, hand, and wrist. The two-part construct is specifically intended for Talonavicular, Calcanealcuboid, Metatarso-Cunieform, Ankle, Capito-Lunate, and Triquetral-Hamate arthrodesis, as well as Metatarsal Osteotemies.
Statement of Technological Comparison	Mechanical Testing and calculations have been completed supporting substantial equivalence to the predicate devices listed. The implants in the EXTREMITY MEDICAL Screw and Washer system have a similar design; are made of similar materials, have the same indications for use, and have equivalent mechanical properties.
Non-clinical Testing	Bench testing, including pull-out strength, torque, and bending, was performed and compared to the predicate devices. Clinical simulations in cadavers were performed to verify the surgical technique. The results of the testing show the subject device, Extremity Medical Screw and Washer system, performed at least as well as the predicate devices.
Clinical Testing	No clinical testing was performed.
Conclusion	The EXTREMITY MEDICAL Screw and Washer System, subject of this submission, as supported by both mechanical testing and clinical simulation, constitutes a safe and effective medical device, meeting all the declared requirements of its intended use. The device presents no adverse health effects or safety risks to patients when used as intended. The EXTREMITY MEDICAL Screw and Washer System performed as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

EXTREMITY MEDICAL
% Jamy Gannoe
President
300 Interpace Parkway, Suite 410
Parsippany, New Jersey 07054

OCT 12 2010

Re: K101700
Trade/Device Name: EXTREMITY MEDICAL Screw and Washer System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: August 31, 2010
Received: September 16, 2010

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Dear Jamy Gannoe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101700

Device Name: EXTREMITY MEDICAL Screw and Washer System

Indications for Use:

The Extremity Medical Screw and Washer System is intended for reduction and internal fixation of arthrodeses, osteotomies, intra- and extrarticular fractures and nonunions of the small bones and joints of the foot, ankle, hand, and wrist. The two-part construct is specifically intended for Talonavicular, Calcanealcuboid, Metatarso-Cunieform, Ankle, Capito-Lunate, and Triquetral-Hamate arthrodesis, as well as Metatarsal Osteotemies.

Prescription Use X **AND/OR** **Over-the-counter** _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101700